Instructions for use

CE
0297

Implantology

Contra-angle
WI-75 E/KM

W&H Symbols

WARNING!
(Risk of injury)

ATTENTION!
Important notes!
(to prevent damage occurring)

General explanations, without risk to persons or objects

Thermo washer disinfectable

Sterilizable up to the stated temperature

Data Matrix Code, only for certain models, for product identification e.g. in hygienic maintenance process

Only for USA
Caution: Federal law restricts this device to sale by or on the order of a dentist, physician or any other practitioner licensed by the law of the State in which he or she practices to use or order the use of the device.

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1. Introduction

Customer satisfaction is the main priority under the W&H quality policy. This W&H product has been developed, manufactured and subjected to final inspection according to legal regulations, quality norms and industry standards.

For your safety and the safety of your patients
Prior to initial use please read the Instructions for Use. These explain how to use your W&H product and guarantee a smooth and efficient operation.

Intended use
Surgical treatment of organic hard matter.
Misuse can damage the implantology contra-angle and involves risk and danger to user and third parties.

Production according to EU directive

CE 0297 This implantology contra-angle is a medical product according to the EU directive 93/42/EEC, implemented by the Austrian Medical Device Act.

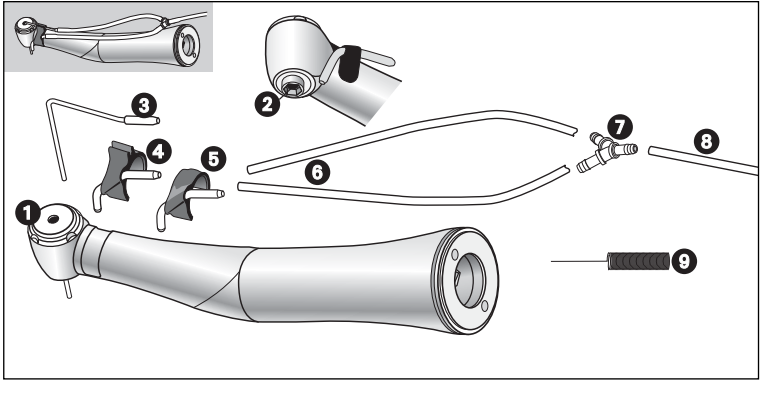
Skilled application

This medical product is intended only for informed use according to their purpose in surgery in compliance with the valid health and safety at work regulations, the valid accident prevention regulations as well as in compliance with these Instructions for Use. The contra-angle should be maintained according to the manufacturer's recommendations and in-line with infection control procedures for the safety and well-being of patients. Improper use, e.g. poor hygienic maintenance, or non-compliance with our Instructions or the use of accessories and spare parts which are not approved by W&H, invalidates all claims under warranty and any other claims.

Service

In case of service or repair contact your local retail dental supplier, or one of our service and sales departments (see page 26). Service and maintenance work must only be carried out by accredited W&H service organizations.

2. Product description



❶ press-button
❷ hexagon chucking system
❸ coolant tube for internal bur cooling
❹ spray clip with external coolant tube
❺ spray clip Exco
❻ coolant hose
❼ Y-manifold
❽ coolant hose of the unit
❾ nozzle cleaner

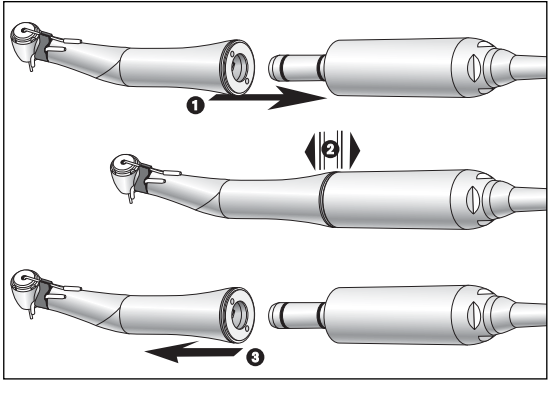
3. Before use – Safety notes

- **CAUTION! The torque setting on the unit must be reduced by approximately half when using the WI-75 E/KM (20:1), for improved efficiency and to prevent injury!** e.g. to obtain 50 Ncm from the rotary instrument you have to set the torque at 30 Ncm on the W&H Elcomed 100/200 (risk of injury)! The implant*M*ED SI-95 is to be adjusted to the WS-75 E/KM. The implant*M*ED SI-915/SI-923 does not need a torque correction.
- The maximum permitted torque of the drive of the WI-75 E/KM is 6 Ncm (risk of damage)!
- The operation of the contra-angle is permitted only on dental units which correspond to the medical device directive.
- Always ensure the correct operating conditions and cooling function.
- Always ensure that sufficient and adequate cooling is delivered and ensure adequate suction. In case of coolant supply failure, the contra-angle must be stopped immediately.
- Check the contra-angle for damage and loose parts prior to use (e. g. press-button).

Hygienic maintenance prior to initial use

The contra-angle is in a clean condition and sealed in PE-film when delivered. Lubricate the contra-angle prior to initial use. Sterilize contra-angle, Y-manifold, coolant tubes, spray clip and coolant tube for internal bur cooling.

– Oil service page 20
– Sterilization page 22



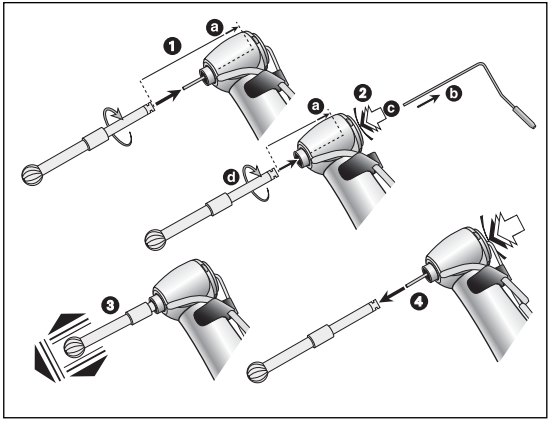
Assembly and removal

Do not assemble/remove the contra-angle during the operation!

❶ Push the contra-angle onto the motor.
– When using a locking pin between motor and instrument: see Instructions for Use of the unit.
❷ Check the secure hold on the motor.
❸ Remove the contra-angle from the motor by pulling in an axial direction or by pressing the release button.

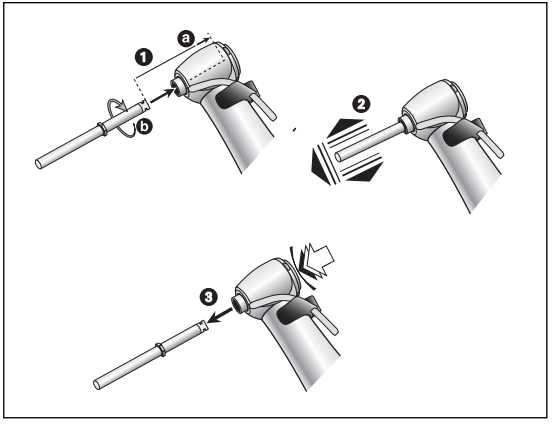
Rotary instruments

– Use only rotary instruments which are in perfect condition and be careful when the rotary instrument is rotating. Follow the operating instructions of the manufacturer.
– Insert rotary instruments only when the contra-angle is stationary.
– Do not interfere with the running or slowing down of rotary instruments.
– Do not activate the press-button of the contra-angle during operation. This leads to detachment of the rotary instrument and makes the head of the contra-angle hot.



To change rotary instrument

1. *using internal bur cooling, rotary instrument ø 2,35 mm:* Insert the rotary instrument over the coolant tube until back stop (a).
2. *without using internal bur cooling, rotary instrument ø 2,35 mm:* Remove the coolant tube for internal bur cooling (b). Insert the rotary instrument into the contra-angle until back stop (a). Activate press-button (c) and turn the rotary instrument until it engages (d).
3. Check secure location by applying slight axial tension.
4. Remove the rotary instrument by pushing the press-button.



To change rotary instrument with hexagon

❶ Insert the rotary instrument until back stop (a) and turn until it engages (b).

❷ Check secure location by applying slight axial tension.

❸ Remove the rotary instrument by pushing the press-button.

Please ask your implant supplier for an applicable rotary instrument with hexagon.

Test run

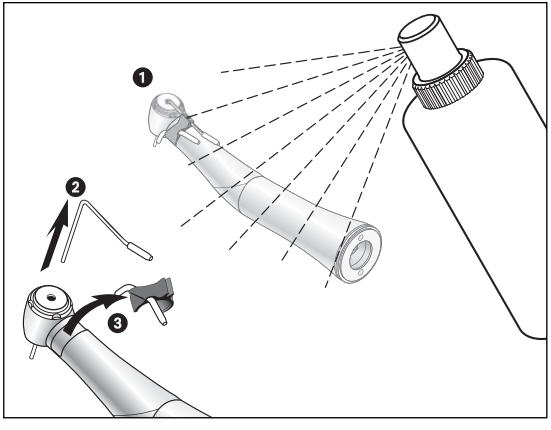
– Insert rotary instrument.
– Start the contra-angle.
– If you observe problems (e.g. vibrations, unusual noise, overheating, coolant supply failure or leakage) get in touch with your service agent (see page 26).

5. Hygienic maintenance

– Disinfect and clean the contra-angle **immediately after every treatment,** to flush out any liquid (like residues of blood, saliva or saline solution), which may have seeped in and to prevent settling on the internal parts.

– You can process the contra-angle manually or mechanically.
– Sterilize the contra-angle following manual or mechanical disinfection, cleaning and lubrication.

– Wear protective gloves.
– Remove the rotary instrument.
– Remove the contra-angle from the motor.

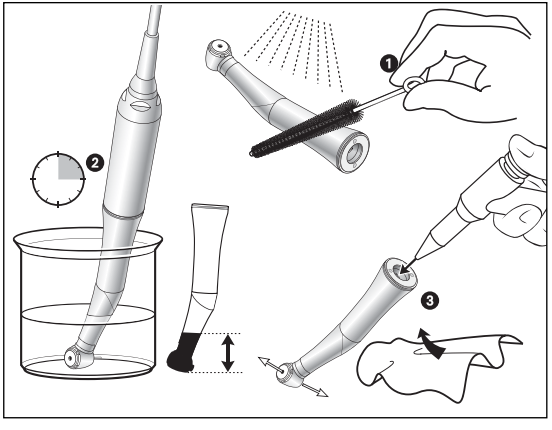


Manual disinfection

– If heavily soiled: Clean first with disinfectant cloths.
– Disinfect using surface disinfectants
  ❶ Spray disinfection is recommended.
– Use certified surface disinfectants (e.g. DGHM-tested). **For USA:** Use EPA registered surface disinfectants.
– Note the action times of the disinfectants used!

To remove spray clip

❷ Remove the coolant tube for internal bur cooling.
❸ Remove the spray clip.



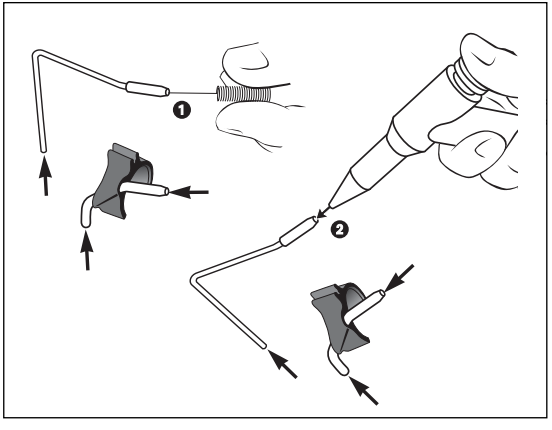
Manual cleaning

❶ Rinse under demineralized water (< 38 °C) with the aid of a brush (not recommended in U.K.)

or

❷ Immerse the head of the contra-angle into demineralized water. Start the contra-angle and run for approx. 15 seconds.

❸ Remove any liquid residues (absorbent cloth, blow dry with compressed air).



Clean external coolant tubes

❶ Clean coolant tubes carefully with the nozzle cleaner to remove dirt and deposits.

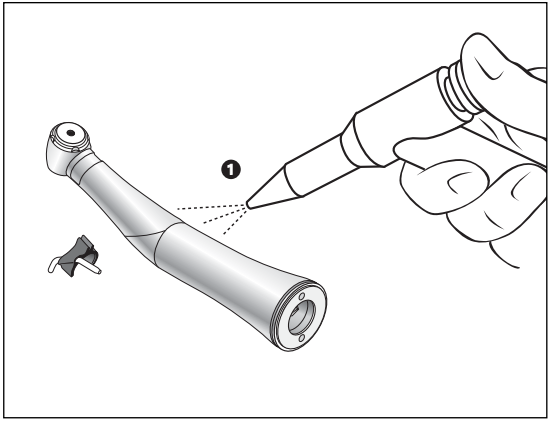
❷ Blow through the coolant tubes with the air syringe.

Mechanical cleaning and disinfection internal and external

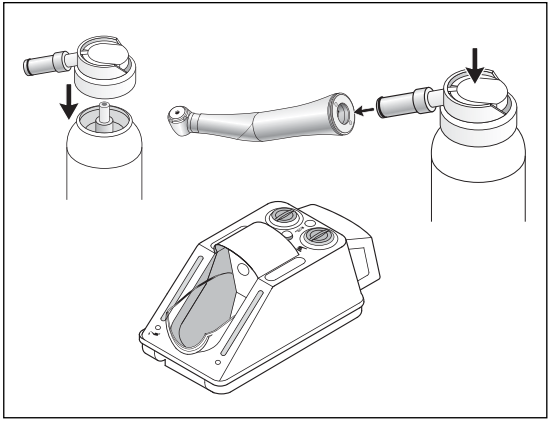
Contra-angles with this symbol can be cleaned and disinfected in a thermo washer disinfector.

W&H recommends processing with thermo washer disinfector.

Lubricate contra-angle immediately after thermo washer disinfection.



– Note the instructions of the unit manufacturer.
– Note the recommendations (which agents to use, and their concentration) of the cleansing agents manufacturer.
– Preliminary cleaning with cold water is recommended (not recommended in U.K.).
– Drying (complete)
  ❶ Remove any liquid residues (blow dry with compressed air).



Daily oil service only with W&H Service Oil F1, MD-400

– Follow the Instructions for Use of the oil spray can.

Daily oil service only with W&H Assistina

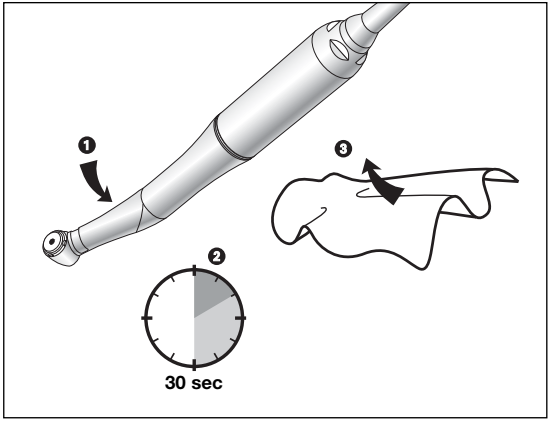
– See Instructions for Use of Assistina.

Recommended lubrication cycles

– essential after every thermo washer disinfection
– before each sterilization

or

– after 60 minutes of use



Test run following oil service

❶ Place the contra-angle with the head downwards.

❷ Start contra-angle for 30 seconds to remove excessive oil. Start at the minimum speed and increase to the maximum speed within 5 to 10 seconds.

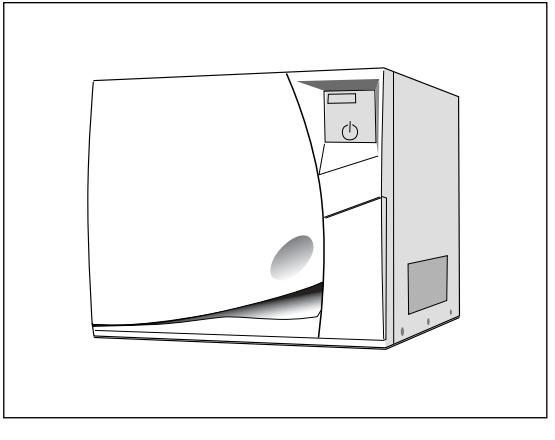
– Repeat the oil service if dirt emerges.

❸ Wipe contra-angle with gauze or soft cloth.

Sterilization and storage

W&H recommends sterilization according to EN 13060, class B

- Note the instructions of the unit manufacturer.
- Only sterilize cleaned and lubricated contra-angles.
- Wrap the contra-angles in sterile goods packaging according to EN 868-5.
- Store sterile goods dust-free and dry.



Permitted sterilization methods

– Steam vacuum sterilization according to EN 13060, using a sterilization holding time of a minimum of 3 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)

or

– Steam gravity sterilization using a sterilization holding time of a minimum of 4 minutes at 134 (+ 3) °C (273.2 + 5.4 °F)

6. W&H Accessories

Use only original W&H accessories and spare parts!

Suppliers: W&H partners

301	W&H Assistina
10940011	W&H Service Oil F1, MD-400
02038200	Spray cap with nozzle for contra-angles
02015101	Short nozzle cleaner (for contra-angles)
02610500	Coolant tube complete (for internal bur cooling)
02653901	Y-manifold
02654700	Coolant hoses (2 pcs)
04757100	Spray clip
05051000	Spray clip Exco

Technical data

Implantology contra-angle		WI-75 E/KM
Transmission ratio		20 : 1
Colour coding		green
Motor coupling according to standard		ISO 3964
Rotary instruments	EN ISO 1797-1 (ø mm)	2.35 **
Length approved by W&H	(mm)	max. 45*
Minimum chucking length	(mm)	engaging
Maximum rated speed	(rpm)	50,000
Spray water volume	ISO 7785-2 (ml/min)	> 50
Maximum torque at rotary instrument	(Ncm)	70 **
Using rotary instrument with hexagon	(Ncm)	105

* When using longer rotary instruments the user must ensure by correct selection of the operating conditions, that there is no danger to the user, patient or third parties.

** When having a torque higher than 30 Ncm on the rotary instrument you have to use hardened shafts (>50 HRC, >520 HV) (risk of deformation).

W&H Contacts

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In other countries
Please contact your distributor or sales representative.

Letter of indemnity

This W&H product has been manufactured with great care by highly qualified specialists. A wide variety of tests and controls guarantee faultless operation. Please note that claims under warranty can only be validated when all the directions in the instructions for use have been followed.

As manufacturer, W&H is liable for material or manufacturing defects within a warranty period of one year from the date of purchase.

We accept no responsibility for damage caused by incorrect handling or by repairs carried out by third parties not authorized to do so by W&H! High-pressure bulbs are excluded from the warranty.

Claims under warranty – accompanied by proof of purchase – must be sent to the vendor or to an authorized W&H service point. The provision of service under warranty extends neither the warranty period nor any other guarantee period.

Manufacturer

ISO 13485, Annex II
93/42/EWG, EC 0297

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